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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,746	04/16/2007	Frank Theodor Gudermann	37998-237472	1040
26694	7590	11/08/2010		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER WHITE, DENNIS MICHAEL	
			ART UNIT 1772	PAPER NUMBER
			MAIL DATE 11/08/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,746

Applicant(s)

GUDERMANN ET AL.

Examiner

DENNIS M. WHITE

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-22 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20-22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed on 10/08/2010 is noted. Claims 1-9, 14, 20-22, 25 are amended. Claims 23-24 are cancelled. Currently claims 1-18, 20-22, and 25-27 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1, 3, 5-18, 20-22, 25-27** are rejected under 35 U.S.C. 102(b) as being anticipated by Bukshpan et al (US 2002/0198928).

Regarding claims **1, 3, 20**, Bukshpan et al teach a method and device for recording microscopic images with high optical resolution of cells ("particles or organisms") disposed on the surface of light sensitive layer 4A on a sample carrier 240 provided with fluidics system 116 ("flow cuvette") on a motorized stage 106. The carrier is scanned by moving the stage motorized stage ("wherein the optical sensor and measuring cell are moving relative to one another while the contents of the measuring cell are imaged" "measuring cell is moving along the sensor".) and the images of the cells disposed on the surface of the layer are acquired by the camera ("recording the image of the suspension by an optical sensor") and stored in memory (Para. 0162). Bukshpan teaches the system 100 may (optionally) further include a fluidics system 116. The fluidics system 116 may include suitable fluidics elements for controllably

adding or removing fluids to the sample carriers ("suspended in a liquid" "introducing the suspension in a measuring cell" "flowing cuvette"). If a developer is not initially included in the solution including the sample cells or particles, the fluidics system 116 may add a suitable developer solution to the samples for performing the development of the photosensitized regions of the layer 4 (Para. 0147).

Regarding claims **5-7**, Bukshpan et al teach the immobilization ("sinking or rising of the objects within the cuvette can be effected by one or more of the following: biological techniques, physical techniques, chemical techniques, sedimentation, and buoyancy") of particles to the light sensitive surface and imaging the adhering particles with the light source on one side and the detector on the other (Para. 0090 and 0129) ("allowing the particles to sink onto the ground of the measuring cell or into a region above the ground, wherein only part of the measuring cell contains the particles or organisms to be examined, imaging the ground or the region above with a high optical resolution, and covering the ground or the region above by the optical sensor" "allowing the particles to rise to an upper limiting surface of the measuring cell or into a region below the upper limiting surface, wherein only part of the measuring cell contains the particles or organisms to be examined, imaging the upper limiting surface or the region below with a high optical resolution, and covering the upper limiting surface or the region below by the optical sensor").

Regarding claims **8-10, 21-22**, Bukshpan et al teach the optical system can be either trans-illumination ("transmitted light illumination, wherein a light source is situated on one side of the measuring cell, and the optical sensor and an objective sensor are

located on the opposite side of the measuring cell" "bright field illumination") (Para. 0129 and Fig. 4A) or epi-illumination ("providing incident light illumination by situating a, light source, an objective, and the optical sensor on the same side of the measuring cell") (Para. 0130).

Regarding claims **11-13, 16, 27**, Bukshpan et al teach the transmitted light can be dark field illumination, phase contrast illumination (Para. 0129) and fluorescence illumination (Para. 0127).

Regarding claims **14-15**, Bukshpan et al teach the illuminating the objects in the measuring cell with a defined spectral intensity distribution of the incident light by a suitable light source or the insertion of one or more suitable filters ("enables the optical sensor to be illuminated with a defined spectral intensity distribution of the incident light") (Para. 0123).

Regarding claim **17**, Bukshpan et al teach the cells can be pre-treated with Giemsa stain ("admixing the suspension with stains prior to the introducing step") (Para. 0230-0234).

Regarding claim **18**, Bukshpan et al teach the using of FITC visualization filter and the use of Cy3 visualization filter for the same field of view (It is noted that "changing the one or more filters automatically or manually" is read on the use of two different filters, since there is a changing either automatically or manually of the filters) (Para. 0359).

Regarding claims **25-26**, Bukshpan et al teach condenser optics 262 and filter 260 are on the same side as the light source ("a screen and lens system on the same

side of the measuring cell as the light source" "the screen and lens system is a condenser") (Para. 0156).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims **2 and 4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bukshpan et al (US 2002/0198928) in view of Ravkin et al (US 2003/0134330).

Bukshpan et al teach the limitations of claim 1 as per above.

Regarding claims **2 and 4**, Bukshpan et al teach the controllably moving the motorized stage for scanning the sample carrier. Bukshpan et al are silent that the camera ("sensor") is moving along the measuring cell and the measuring cell is imaged onto said optical sensor by the movement of optical elements.

Ravkin et al teach a method for multiplexed detection of analytes by reacting them with probe molecules attached to carriers. Ravkin et al teach the method includes sensing trans-illumination such as absorbance or microscope pattern such as bright field, dark field, or phase contrast or epi-illumination such as to detect fluorescence. Ravkin teach the light source and the detector can be on the same side of the carrier such as a microplate for the epi-illumination or positioned on opposite sides of the carrier for trans-illumination. Ravkin et al further teach the detector may detect light by moving from well(s) to well(s), through movement of the detector, the sample holder, or both. Accordingly, detector 1918 may be fixed or may be configured to move relative to microplate 1912, to enable scanning. When detector 1918 is fixed, stage 1920 may be configured to move portions of microplate 1912 past detector 1918. In some embodiments, an optical element (see below) may be movable to direct light from different portions of the microplate to the detector.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary

skill in the art to substitute the step of moving the detector of Ravkin et al for the step of moving the stage of Bukshpan because they are equivalent steps to scan sample carriers in order measure trans-illumination or epi-illumination assays.

Response to Arguments

8. Applicant's arguments filed 10/8/2010 have been fully considered but they are not persuasive. Applicants argue that Bukshpan et al fails to teach a device and method in which a flow cuvette and an optical sensor move relative to one another during the optical recording of microscopic images. It is noted that Buckshpan et al teaches a sample carrier 240 provided with fluidics system 116 ("flow cuvette") on a motorized stage 106 and the carrier is scanned by moving the stage motorized stage. It is noted that in the absence of further defining a flow cuvette, the limitation is sufficiently broad to read on the sample carrier 240 with the fluidic system 116 of Buckspan. Therefore all the claim limitations have been met by Buckspan as per above.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571) 270-3747. The examiner can normally be reached on Monday-Thursday, EST 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571) 272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1773

/dmw/

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